PATENT

Applicant: **Williams et al.**
Serial No.: **09/553223**
Filed: **4/20/2000**
Title: **A COMBINED RAPID ANTI-MICROBIAL SUSCEPTIBILITY ASSAY & MICROORGANISM IDENTIFICATION SYSTEM**
Group Art Unit: **1651**
Examiner: **H. Gutman**
Docket No.: **14598.34**

11/B
H.G.
4/24/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231

RESPONSE TO OFFICE ACTION

Sir:

Please cancel claims 22-26. Add new claims 43-52

Sub C1

43. A method for the parallel determination of a microorganism's identity and susceptibility to an anti-microbial agent comprising:

preparing a sample to be tested;

inoculating a hybrid panel having a plurality of reaction chambers with said sample, wherein said hybrid panel comprises reaction chambers for determining said microorganism's identity in parallel with reaction chambers for determining said microorganism's susceptibility to at least one antimicrobial agent;

B1

placing said inoculated hybrid panel into a device that maintains said inoculated hybrid panels at a predetermined temperature;

incubating said inoculated hybrid panel in said device at said predetermined temperature for a first predetermined time;

reading said reaction chambers for determining said microorganism's identity at said first predetermined time by directing a fluorescent light source through

said reaction chambers for determining said microorganism's identity and collecting resulting fluorescent signals;

converting said fluorescent signals into artificial fluorescent units (AFUs) and recording said AFUs;

analyzing said AFUs using a database to establish said microorganism's identity and retaining said identity until said microorganism's susceptibility to at least one antimicrobial is determined;

reading said reaction chambers for determining said microorganism's susceptibility at least one second predetermined time by transmitting a visible light source through said reaction chambers for determining said microorganism's susceptibility to at least one antimicrobial agent, collecting said resulting visible light signals and converting said visible light signals into a turbidity reading;

analyzing said turbidity reading according to the algorithm depicted in Figure 1;

determining said microorganism's susceptibility to at least one antimicrobial agent as directed by the algorithm depicted in Figure 1; and

retaining said parallel determinations of said antimicrobial sensitivity and said microorganism's identity such that said antimicrobial sensitivity and microorganism's identity can be reported.

44. The method according to claim 43 wherein said sample comprises a substantially pure culture of microorganisms suspended in inoculum water.

45. The method according to claim 44 wherein said inoculum water consists essentially of purified water and a detergent.

46. The method according to claim 44 wherein said sample is standardized to contain between approximately 1 $x10^5$ microorganisms per mL to approximately 1 X 10^8 microorganisms per milliliter (mL) of said inoculum water..

47. The method according to claim 43 wherein said reading said reaction chambers for determining said microorganism's susceptibility is done manually.

48. The method according to claim 43 wherein said reading said reaction chambers for determining said microorganism's susceptibility is done instrumentally in an automated system.

49. The method according to claim 43 wherein said converting said visible light signals into a turbidity reading is done using a microprocessor.

50. The method according to claim 43 wherein said converting of said fluorescent signals into AFUs and recording said AFUs is done using a microprocessor.

51. The method according to claim 43 retaining of said parallel determinations of said antimicrobial sensitivity and said microorganism's identity is performed using a microprocessor.

52. The method according to claim 43 wherein said incubating step, reading steps, converting steps, analyzing steps, determining step and retaining steps are done using an automated system.

Remarks

Information Disclosure Statement

The Applicant acknowledges that the references listed in the PTO-1449 submitted July 23, 2001 have not been found. Furthermore, the Applicant's attorney acknowledges that he was requested to FAX the documents to the examiner and that he has not. The documents requested are voluminous and therefore the Applicant's attorney hereby submits them with this Request for Continued Examination.

Rejections Under 35 U.S.C. §112

In his Final Office Action, paper 8, dated December 14, 2001, the Examiner rejected claims 22-36 under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Applicant believes that the basis for this rejection has been addressed in new claims 43-52 and therefore respectfully asserts that the rejection(s) of December 14, 2001 have been rendered moot.

Rejections Under 35 U.S.C. §103

In his Final Office Action, paper 8, dated December 14, 2001, the Examiner rejected claims 22-36 under 35 U.S.C. §103(a) as being unpatentable over Thompson, et al. (US5,164,301) in view of Clark et al. (WO98/5331) and the Fisher Biotechnology Catalog (1995, page 114 and 116).

Briefly, the Examiner has stated that Thompson teaches a microtiter-based antimicrobial susceptibility assay wherein an minimum inhibitory concentration (MIC)